

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

C.A. No. 07-572-GMS

ACTAVIS SOUTH ATLANTIC LLC,
AUROBINDO PHARMA LTD.,
AUROBINDO PHARMA USA INC.,
MYLAN PHARMACEUTICALS INC., PAR
PHARMACEUTICALS INC., RANBAXY
INC., RANBAXY LABORATORIES
LIMITED, SUN PHARMACEUTICAL
INDUSTRIES, INC., SUN
PHARMACEUTICAL INDUSTRIES LTD,
TEVA PHARMACEUTICALS USA, INC.
TORRENT PHARMA INC. and TORRENT
PHARMACEUTICALS LIMITED,

Defendants.

TEVA PHARMACEUTICALS USA, INC.'S ANSWER AND COUNTERCLAIMS

Defendant, Teva Pharmaceuticals USA, Inc. ("Teva"), by its attorneys, for its answer
responds as follows:

PARTIES

1. Teva is without information sufficient to form of belief as to the truth or falsity of the allegations in paragraph 1 of the Complaint, and therefore, denies them.
2. Teva is without information sufficient to form of belief as to the truth or falsity of the allegations in paragraph 2 of the Complaint, and therefore, denies them.

3. Teva is without information sufficient to form of belief as to the truth or falsity of the allegations in paragraph 3 of the Complaint, and therefore, denies them.

4. Teva is without information sufficient to form of belief as to the truth or falsity of the allegations in paragraph 4 of the Complaint, and therefore, denies them.

5. Teva is without information sufficient to form of belief as to the truth or falsity of the allegations in paragraph 5 of the Complaint, and therefore, denies them.

6. Teva is without information sufficient to form of belief as to the truth or falsity of the allegations in paragraph 6 of the Complaint, and therefore, denies them.

7. Teva is without information sufficient to form of belief as to the truth or falsity of the allegations in paragraph 7 of the Complaint, and therefore, denies them.

8. Teva is without information sufficient to form of belief as to the truth or falsity of the allegations in paragraph 8 of the Complaint, and therefore, denies them.

9. Teva is without information sufficient to form of belief as to the truth or falsity of the allegations in paragraph 9 of the Complaint, and therefore, denies them.

10. Teva is without information sufficient to form of belief as to the truth or falsity of the allegations in paragraph 10 of the Complaint, and therefore, denies them.

11. Teva is without information sufficient to form of belief as to the truth or falsity of the allegations in paragraph 11 of the Complaint, and therefore, denies them.

12. Teva admits paragraph 12 of the complaint.

13. Teva is without information sufficient to form of belief as to the truth or falsity of the allegations in paragraph 13 of the Complaint, and therefore, denies them.

14. Teva is without information sufficient to form of belief as to the truth or falsity of the allegations in paragraph 14 of the Complaint, and therefore, denies them.

NATURE OF ACTION

15. In response to paragraph 15, Teva admits that the Complaint purports to be a civil action for patent infringement of U.S. Patent Nos. 4,661,491 (“the ‘491 patent’”) and 6,149,940 (“the ‘940 patent’”), that copies of both patents are attached as Exhibits A and B respectively to the Complaint, and that this is an action based upon the patent laws of the United States.

JURISDICTION AND VENUE

16. In response to paragraph 16, Teva admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a).

17. In response to paragraph 17, Teva admits that this Court has personal jurisdiction over it, but denies that it has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement or that any such act has led to harm or injury to Plaintiff Sanofi-Aventis U.S. To the extent that paragraph 17 is directed towards other defendants, Teva lacks sufficient information to form a belief as to the truth or falsity of such allegations and therefore denies them.

18. The allegations in paragraph 18 are not directed to Teva and therefore no response is required on behalf of Teva.

19. The allegations in paragraph 19 are not directed to Teva and therefore no response is required on behalf of Teva.

20. The allegations in paragraph 20 are not directed to Teva and therefore no response is required on behalf of Teva.

21. The allegations in paragraph 21 are not directed to Teva and therefore no response is required on behalf of Teva.

22. The allegations in paragraph 22 are not directed to Teva and therefore no response is required on behalf of Teva.

23. The allegations in paragraph 23 are not directed to Teva and therefore no response is required on behalf of Teva.

24. The allegations in paragraph 24 are not directed to Teva and therefore no response is required on behalf of Teva.

25. The allegations in paragraph 25 are not directed to Teva and therefore no response is required on behalf of Teva.

26. The allegations in paragraph 26 are not directed to Teva and therefore no response is required on behalf of Teva.

27. Teva admits paragraph 27 of the Complaint.

28. The allegations in paragraph 28 are not directed to Teva and therefore no response is required on behalf of Teva.

29. The allegations in paragraph 29 are not directed to Teva and therefore no response is required on behalf of Teva.

30. In response to paragraph 30, Teva admits that venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS

31. In response to paragraph 31, Teva admits that the '491 patent on its face is titled "Alfuzosine Compositions and Use," but denies that such patent was "duly and legally issued." Teva is without sufficient information to admit or deny that Plaintiff Sanofi-Aventis U.S. is the current assignee of the '491 patent and therefore denies the same. Teva admits that the Orange Book lists Plaintiffs Sanofi-Aventis U.S. as the applicant for New Drug Application ("NDA")

No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended release 10mg tablets, and that the '491 patent is listed for Uroxatral®. Teva is without sufficient information to admit or deny that Plaintiff Sanofi-Aventis U.S. holds NDA No. 21-287, or is the exclusive U.S. distributor of Uroxatral® and therefore denies the same.

32. In response to paragraph 32, Teva admits that the '940 patent on its face is titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate." Teva lacks sufficient information to admit or deny that the '940 patent was "duly and legally issued." Teva lacks sufficient information to admit or deny that Plaintiffs Sanofi-Aventis and Jagotec AG are the current assignees of the '940 patent and therefore denies the same. Teva is without sufficient information to admit or deny whether Plaintiff Sanofi-Aventis has an exclusive right to unilaterally bring and proceed with this action in its own name, or whether Jagotec has also so consented and therefore denies the same. Teva admits that the '940 patent is listed in the Orange Book for Uroxatral®.

ACTS GIVING RISE TO THIS ACTION

COUNTS I – VIII – ALLEGED INFRINGEMENT OF THE '491 PATENT BY STATED DEFENDANTS OTHER THAN TEVA

33. The allegations in paragraphs 33 through 84 are not directed to Teva and therefore no response is required.

COUNT IX – ALLEGED INFRINGEMENT OF THE '491 PATENT BY DEFENDANT TEVA

34. Teva admits the allegations of paragraph 85 of the Complaint.

35. In response to paragraph 86 of the Complaint, Teva admits that its ANDA No. 79-056 certifies that the claims of the '491 patent are invalid and would not be infringed by the manufacture, use or sale of its proposed ANDA product. Teva further admits that each named plaintiff received written notification of its ANDA No. 79-056 on August 15, 2007.

36. In response to paragraph 87 of the Complaint, Teva admits that the preparation and filing of its ANDA No. 79-056 is a technical act of infringement under 35 U.S.C. § 271(e)(2)(A) which creates jurisdiction for this Court to determine that its proposed ANDA product, if used, offered for sale, or sold in the United states, would not infringe any valid claim of the '491 patent. Teva denies any remaining allegations stated or implied by paragraph 87 of the Complaint.

37. Teva denies paragraph 88 of the Complaint.

38. Teva denies paragraph 89 of the Complaint.

COUNT X – ALLEGED INFRINGEMENT OF THE '940 PATENT
BY DEFENDANT TEVA

39. Teva admits the allegations of paragraph 90 of the Complaint.

40. In response to paragraph 91 of the Complaint, Teva admits that its ANDA No. 79-056 certifies that the claims of the '940 would not be infringed by the manufacture, use or sale of its proposed ANDA product. Teva further admits that each named plaintiff received written notification of its ANDA No. 79-056 on August 15, 2007.

41. In response to paragraph 92 of the Complaint, Teva admits that the preparation and filing of its ANDA No. 79-056 is a technical act of infringement under 35 U.S.C. § 271(e)(2)(A) which creates jurisdiction for this Court to determine that its proposed ANDA product, if used, offered for sale, or sold in the United states, would not infringe the '940 patent. Teva denies any remaining allegations stated or implied by paragraph 92 of the Complaint.

42. Teva denies paragraph 93 of the Complaint.

43. Teva denies paragraph 94 of the Complaint.

**COUNT XI – XII ALLEGED INFRINGEMENT OF THE '491 PATENT BY
REMAINING STATED DEFENDANTS**

44. The allegations in paragraphs 95 through 108 are not directed to Teva and therefore no response is required.

PRAYER FOR RELIEF

A. Teva denies that Plaintiffs are entitled to the relief requested in paragraph A of the Prayer for Relief in the Complaint as it pertains to Teva and lacks sufficient information to admit or deny the propriety of the requested relief as to the other named defendants and therefore denies the same.

B. Teva denies that Plaintiffs are entitled to the relief requested in paragraph B of the Prayer for Relief in the Complaint as it pertains to Teva and lacks sufficient information to admit or deny the propriety of the requested relief as to the other named defendants and therefore denies the same.

C. Teva denies that Plaintiffs are entitled to the relief requested in paragraph C of the Prayer for Relief in the Complaint as it pertains to Teva and lacks sufficient information to admit or deny the propriety of the requested relief as to the other named defendants and therefore denies the same.

D. Teva denies that Plaintiffs are entitled to the relief requested in paragraph D of the Prayer for Relief in the Complaint as it pertains to Teva and lacks sufficient information to admit or deny the propriety of the requested relief as to the other named defendants and therefore denies the same.

E. Teva denies that Plaintiffs are entitled to the relief requested in paragraph E of the Prayer for Relief in the Complaint as it pertains to Teva and lacks sufficient information to admit

or deny the propriety of the requested relief as to the other named defendants and therefore denies the same.

F. Teva denies that Plaintiffs are entitled to the relief requested in paragraph F of the Prayer for Relief in the Complaint as it pertains to Teva and lacks sufficient information to admit or deny the propriety of the requested relief as to the other named defendants and therefore denies the same.

G. Teva denies that Plaintiffs are entitled to the relief requested in paragraph G of the Prayer for Relief in the Complaint as it pertains to Teva and lacks sufficient information to admit or deny the propriety of the requested relief as to the other named defendants and therefore denies the same.

H. Teva denies that Plaintiffs are entitled to the relief requested in paragraph H of the Prayer for Relief in the Complaint as it pertains to Teva and lacks sufficient information to admit or deny the propriety of the requested relief as to the other named defendants and therefore denies the same.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

1. The claims of the '491 patent are invalid under 35 U.S.C. § 103.

SECOND AFFIRMATIVE DEFENSE

2. The manufacture, use, or sale of Teva's ANDA product has not infringed, does not infringe, and would not, if approved by the FDA and marketed, infringe directly, through contributory infringement, or by inducement any claim of the '491 patent.

THIRD AFFIRMATIVE DEFENSE

3. The manufacture, use, or sale of Teva's ANDA product has not infringed, does not infringe, and would not, if approved by the FDA and marketed, infringe directly, through contributory infringement, or by inducement any claim of the '940 patent.

FOURTH AFFIRMATIVE DEFENSE

4. Counts IX - X of the Amended Complaint fail to state a claim for relief upon which relief can be granted against Teva.

FIFTH AFFIRMATIVE DEFENSE

5. Plaintiffs claims for injunctive relief associated with Counts IX - X of the Amended Complaint are barred by the fact that Plaintiffs have an adequate remedy at law.

SIXTH AFFIRMATIVE DEFENSE

6. Counts IX - X of the Complaint fail to state a claim justifying a claim that this case is exceptional under 35 U.S.C. § 285 or for any award of attorney fees.

SEVENTH AFFIRMATIVE DEFENSE

7. Plaintiffs have failed to join Jagotec AG, a co-assignee of the '940 patent and a party whose joinder to this matter is needed for a just adjudication of Teva's alleged liability and asserted defenses to that patent.

TEVA USA COUNTERCLAIMS

Teva, for its Counterclaims against Plaintiffs, alleges as follows:

JURISDICTION

1. This is a declaratory judgment action under 28 U.S.C. §§ 2201 and 2202. The counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1 *et. seq.* and under the food and drug laws of the United States, 21 U.S.C. § 355.

2. Jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

3. Venue is proper in this judicial district as to each named counterclaim defendant pursuant to 20 U.S.C. § 1391.

4. Plaintiffs filed this lawsuit against Teva in this judicial district, alleging infringement of United States Patent Nos. 4,661,491 (“the ‘491 patent”) and 6,149,940 (“the ‘940 patent”).

THE PARTIES

5. Teva is a Delaware corporation, having a principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, PA 19454-1090.

6. Upon information and belief, Sanofi-Aventis (“Sanofi-Aventis”) is a corporation organized and existing under the laws of France, having a place of business at 174 avenue de France, Paris, France 75013.

7. Upon information and belief, Sanofi-Aventis U.S. (“Sanofi-Aventis U.S.”) is a limited liability company organized and existing under the laws of Delaware, having a place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

8. Upon information and belief, Sanofi-Aventis U.S. is the current assignee of the ‘491 patent.

9. Upon information and belief, Sanofi-Aventis and Jagotec AG are the current assignees of the '940 patent.

10. Upon information and belief, Sanofi-Aventis US holds an approved New Drug Application from the FDA for 10mg extended release tablets containing alfuzosin hydrochloride, NDA No. 21-287.

BACKGROUND

11. Teva filed ANDA Application No. 79-056 with the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) (hereafter "Teva's ANDA No. 79-056").

12. The product that is the subject of Teva's ANDA No. 79-056 is a 10mg Alfuzosin Hydrochloride Extended-Release Tablet, which counterclaim defendants Sanofi, Sanofi U.S., and Jagotec allege would infringe the '491 and '940 patents.

13. Sanofi-Aventis listed the '491 and '940 patents in the Orange Book in connection with NDA No. 20-468.

14. Because Teva seeks FDA approval to market its ANDA product before expiration of the '491 and '940 patents, Teva's ANDA includes a certification under 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) as to both patents.

15. On August 14, 2007, Teva sent to Plaintiffs a statutorily-required notice letter of its paragraph IV certifications, which contains a detailed factual and legal statement as to the basis of Teva's ANDA certification.

16. On September 21, 2007, plaintiffs filed this patent infringement lawsuit against Teva, alleging that Teva's ANDA product would infringe the '491 and '940 patents.

COUNTERCLAIM I

DECLARATION OF INVALIDITY OF THE '491 PATENT

17. Teva realleges and incorporates by reference the allegations of paragraphs 1-16 of its Counterclaims.

18. A present, genuine, and justiciable controversy exists between Teva and the Counterclaim Defendants regarding, *inter alia*, the validity of the '491 patent.

19. All claims of the '491 patent are invalid under 35 U.S.C. §103.

20. Teva is entitled to a declaration that claims of the '491 patent are invalid.

COUNTERCLAIM II

DECLARATION OF NON-INFRINGEMENT OF THE '491 PATENT

21. Teva realleges and incorporates by reference the allegations of paragraphs 1 -16 of its Counterclaims.

22. A present, genuine, and justiciable controversy exists between Teva and the Counterclaim Defendants regarding, *inter alia*, whether the manufacture, use, or sale of Teva's proposed ANDA product would infringe any claim of the '491 patent.

23. The manufacture, use, or sale of Teva's ANDA product would not infringe any claim of the '491 patent.

24. Teva is entitled to a declaration that the manufacture, use, or sale of its ANDA products would not infringe claims of the '491 patent.

COUNTERCLAIM III

DECLARATION OF NON-INFRINGEMENT OF THE '940 PATENT

25. Teva realleges and incorporates by reference the allegations of paragraphs 1-16 of its Counterclaims.

26. A present, genuine, and justiciable controversy exists between Teva and Counterclaim Defendants regarding, *inter alia*, whether the manufacture, use, or sale of Teva's proposed ANDA product would infringe any claim of the '940 patent.

27. The manufacture, use, or sale of Teva's ANDA products would not infringe any claim of the '940 patent.

28. Teva is entitled to a declaration that the manufacture, use, or sale of its ANDA products would not infringe claims of the '940 patent.

REQUEST FOR RELIEF

WHEREFORE, Defendant/Counterclaim Plaintiff Teva respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs/Counterclaim Defendants Sanofi-Aventis and Sanofi-Aventis U.S. as follows:

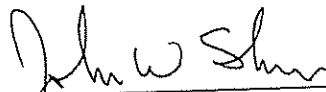
- (a) declaring that the '491 patent is invalid;
- (b) declaring that Teva has not infringed and that Teva's manufacture, use, or sale of products covered by ANDA No. 79-056 would not infringe the claims of the '491 patent;
- (c) ordering that Plaintiffs/Counterclaim Defendants Sanofi-Aventis and Sanofi-Aventis U.S. and each of their respective officers, agents, servants, employees, and those persons or entities in active concert, privity, or participation with them are permanently enjoined from any further charges of infringement or acts of enforcement based on the '491 patent against Teva, its actual or prospective customers, suppliers, clinical investigators, and any other person or entity in privity with Teva;

- (d) declaring that Teva has not infringed and that Teva's manufacture, use, or sale of products covered by ANDA No. 79-056 would not infringe the claims of the '940 patent;
- (e) ordering that Plaintiffs/Counterclaim Defendants Sanofi-Aventis and Sanofi-Aventis U.S. and each of their respective officers, agents, servants, employees, and those persons or entities in active concert, privity, or participation with them are permanently enjoined from any further charges of infringement or acts of enforcement based on the '940 patent against Teva, its actual or prospective customers, suppliers, clinical investigators, and any other person or entity in privity with Teva;

- (f) ordering that Teva be awarded any further and additional relief as the Court deems just and proper.

Respectfully submitted,

TEVA PHARMACEUTICALS USA, INC.



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Teva Pharmaceutical Industries, Ltd.

Dated: October 22, 2007

CERTIFICATE OF SERVICE

I, John W. Shaw, hereby certify that October 22, 2007, I caused a copy of the foregoing document to be served on the counsel listed by the following in the manner:

BY CM/ECF, E-MAIL & HAND DELIVERY

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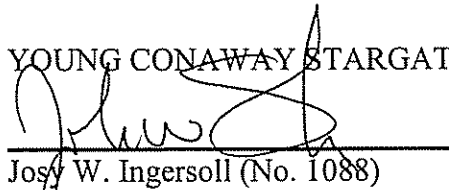
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